FDA 510(k), Premarket Notification: 510(k) Summary of Safety and Effectiveness Information

1.0 Submitter:

Kossan Latex Industries (M) Sdn Bhd
Lot 6129, Jalan Haji Abdul Manan,
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2.0 Contact Person:

Contact: Ms S F Cho
Telephone No.: +603 3392 3088
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3.0 Preparation Date: 29 November 2012

4.0 Name of Device:

Trade Name: Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim.
Common Name: Powder-Free Nitrile Patient Examination Glove
Classification Name: Patient Examination Glove (21 CFR Part 880.6250)
Regulatory Class: *Class I*
Product Code: *80 LZC, 80 LZA.*

5.0 Identification of the Legally Marketed Device:

Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim; Class I Patient Examination Gloves, Nitrile-80LZA, 80LZC, meets all of the requirements of ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

Predicate Device: K120066, Powder Free Nitrile Patient Examination Glove, Blue, White, Green. Non-Sterile. Low Dermatitis Potential Labeling Claim.

6.0 Description of Device:

Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim, meets all of the requirements of ASTM D 6319-10.

7.0 Intended Use of the Device:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

This glove has been tested for use with specific chemotherapy drugs listed below.

Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)	
Dacarbazine (DTIC) (10.0 mg/ml)	> 240
Carmustine (BCNU) (3.3 mg/ml)	**15.3**
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	> 240
Doxorubicin Hydrochloride (2.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Cisplatin (1.0 mg/ml)	> 240
Etoposide (20.0 mg/ml)	> 240
Paclitaxel (Taxol) (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	**195.8**

Warning: Do not use with Carmustine.

8.0 Summary of the Technological Characteristics of the Device:

Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim possess the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards	Device Performance
Dimensions	ASTM D 6319-10	Meets
Physical Properties	ASTM D 6319-10	Meets
Freedom from pin-holes	ASTM D 5151-11 ASTM D 6319-10	Meets Meets
Powder Free Residue	ASTM D 6124-11 ASTM D 6319-10	Meets Meets
Biocompatibility	Dermal Sensitization (as per ISO 10993-10:2010)	Not a contact skin sensitizer
	Primary Skin Irritation Test (as per 16 CFR Part 1500.41)	Not a primary skin irritant

Characteristic	Standards	Device Performance
Low Dermatitis Potential	Modified Draize-95 Test	No clinical evidence presence of residual chemical additives that may induce Type IV allergy in human subjects.
Chemotherapy Drugs Permeation Test	ASTM D6978-05	Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes) Dacarbazine (DTIC) (10.0 mg/ml) > 240 **Carmustine (BCNU) (3.3 mg/ml) 15.3** Cyclophosphamide (Cytoxan) (20.0 mg/ml) > 240 Doxorubicin Hydrochloride (2.0 mg/ml) > 240 Fluorouracil (50.0 mg/ml) > 240 Cisplatin (1.0 mg/ml) > 240 Etoposide (20.0 mg/ml) > 240 Paclitaxel (Taxol) (6.0 mg/ml) > 240 Thiotepa (10.0 mg/ml) 195.8

9.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Testing was performed per ASTM D6319-10, ASTM D5151-11, ASTM D6124-11, ISO 10993-10:2010, and 16 CFR Part 1500.41. The gloves meet standard requirements referenced in Section 8.0 above. Biocompatibility test indicates the gloves are not a contact skin sensitizer and not a primary skin irritant.

10.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim, were tested in accordance with Modified Draize-95 Test, per FDA's guidance document "Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products, 1999".

The study was conducted in two stages. In the first stage, a population of 50 human subjects was tested to evaluate the product for the potential to cause irritation or sensitization. The second stage was initiated on a further number of subjects to a total of a minimum of 200 individuals after the first stage has shown that the test product does not indicate a potential for inducing dermal irritation and does not shown sensitization capability.

The study completed on 200 non-sensitized adult human subjects, who reasonably reflect the general user population in the US, gave all negative results. There was no clinical evidence of the presence of residual chemical additives at the level that may induce Type IV allergy in the un-sensitized general user population in the tested article.

11.0 Conclusion

It can be concluded that Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim is safe and effective for use, and perform according to the glove performance standards referenced in Section 8.0 above, thereby meeting ASTM standards, FDA requirements, and the labeling claims for the product.

This device is identical and substantially equivalent to currently marketed devices, per Substantial Equivalence Comparison Table below:-

Substantial Equivalence Comparison Table

Feature	K120066, Powder Free Nitrile Patient Examination Glove, Blue, White and Green Colored, Non-Sterile (Low Dermatitis Potential Labeling Claim) of Kossan Latex Industries Sdn Bhd **Predicate Device**	Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim **Proposed Device**
Intended Use	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Identical
Indications for Use	This glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. This glove has been tested for use with specific chemotherapy drugs listed below. Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes) Dacarbazine (DTIC) (10.0 mg/mL) >240 **Carmustine (BCNU) (3.3 mg/mL)** 15.3 Cyclophosphamide (Cytoxan) (20.0 mg/mL) >240 Doxorubicin Hydrochloride (2.0 mg/mL) >240 Fluorouracil (50.0 mg/mL) >240 Etoposide (20.0 mg/mL) >240 Paclitaxel (taxol) (6.0 mg/mL) >240 Thio-Tepa (10.0 mg/mL) 195.8 **Warning**: Do not use with Carmustine.

Feature	K120066, Powder Free Nitrile Patient Examination Glove, Blue, White and Green Colored, Non-Sterile (Low Dermatitis Potential Labeling Claim) of Kossan Latex Industries Sdn Bhd Predicate Device	Powder Free Nitrile Patient Examination Glove, Green, Non-Sterile, Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim Proposed Device
Material	Nitrile	Identical
Color	Blue, White and Green	Green
Single Use	Yes	Identical
Sterilization	Not Applicable; Non-Sterile	Identical
Dimensions	Meets ASTM D6319	Identical
Physical Properties	Meets ASTM D6319	Identical
Freedom from Pinholes	Meets ASTM D5151 and ASTM D6319	Identical
Residue Powder	Meets ASTM D6124 and ASTM D6319	Identical
Biocompatibility Test	Pass Dermal Sensitization Test Pass Primary Skin Irritation Test	Identical
Human Draize Test	Pass	Identical
Chemotherapy Drugs Permeation Test	Not Applicable; Not Tested	Meets ASTM D6978-05
Labeling Claim	Low Dermatitis Potential Labeling Claim	Proposed device With Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Ms. Cho Sow Fong
Manager, Regulatory Affairs
Kossan Latex Industries (M) Sdn Bhd
Lot 16632, 5¼ Miles, Jalan Meru
Klang
Selangor, Malaysia 41050

Re: K123749
Trade/Device Name: Powder Free Nitrile Examination Gloves, Green, Non Sterile. Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs Labeling Claim.
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: January 21, 2013
Received: January 25, 2013

Dear Ms. Fong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123749

Device Name: Powder Free Nitrile Patient Examination Gloves, Green, Non-Sterile.
Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs Labeling Claim.

Indications for Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
This glove has been tested for use with specific chemotherapy drugs listed below.

Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)

Dacarbazine (DTIC) (10.0 mg/ml)	> 240
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Etoposide (20.0 mg/ml)	> 240
Paclitaxel (Taxol) (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	**195.8**

Please note that Carmustine has extremely low permeation times of 15.3 minutes.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Elizabeth F Claverie
2013.02.27 17:10:04 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123749